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### REMARKS

Claims 5, 8-12 and 15-30 are all the claims presently pending in the application. Claims 5, 8, 11, 12, 15, 22, 26 and 27 have been amended to more particularly define the invention. Claims 28-30 have been added to claim additional features of the invention.

It is noted that the claim amendments are made only for more particularly pointing out the invention, and not for distinguishing the invention over the prior art, narrowing the claims or for any statutory requirements of patentability. Further, Applicant specifically states that no amendment to any claim herein should be construed as a disclaimer of any interest in or right to an equivalent of any element or feature of the amended claim.

Claims 5, 8-12, 15 and 17-27 stand rejected because the claims are directed to non-statutory subject matter. Claims 5, 8-12 and 15-27 upon informalities (e.g., 35 U.S.C. § 112, first and second paragraphs) and 5, 8-12 and 15-27 stand rejected on prior art grounds. Claims 5, 8-12 and 15-27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dollinger (U.S. Patent No. 5,451,505).

These rejections are respectfully traversed in the following discussion.

#### **I. THE CLAIMED INVENTION**

The claimed invention (e.g., as recited in claim 5) is directed to DNA having embedded information. The DNA includes a gene portion including genetic information, a portion, other than the gene portion, including no genetic information, and a nucleotide sequence which is embedded in the portion including no genetic information, and includes source identification information for identifying a source of the genetic information in the gene portion. Importantly, the nucleotide sequence is embedded so as not to affect transmission of the genetic information.

Conventional DNA does not include any information therein to determine the source of genetic information (e.g., a value-added gene). Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of value-added genes.

The claimed invention, on the other hand, includes a nucleotide sequence which is

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embedded in a portion of the DNA which includes no genetic information, and which includes source identification information for identifying a source of the genetic information in the gene portion. This nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party. Therefore, the claimed invention helps to prevent illegal copying of such genetic information (e.g., a value-added gene).

## II. THE 35 USC §101 REJECTION

The Examiner alleges that the claimed invention, as recited in claims 5 and 8-12, 15 and 17-27 is directed to non-statutory subject matter. However, Applicant submits that the subject matter of these claims is patentable.

Applicant respectfully submits that this rejection was adequately traversed in the Amendment filed herein on October 14, 2003. Therefore, the arguments contained therein are not repeated herein but are incorporated herein by reference.

The Examiner again surprisingly states that "the claims in their broadest and reasonable interpretation do not necessarily include human intervention". The Examiner attempts to support this statement by merely stating that "claim 5 states 'DNA to which information is added' which can occur via evolution or mutation that is independent of the hands of man".

Applicant would point out that the Examiner completely ignores much of Applicant's argument. Indeed, nowhere does the Examiner respond to Applicant's argument that the nucleotide sequence added to a portion of DNA is not just any old nucleotide sequence, but instead includes "source identification information" for identifying a source of the genetic information in the gene portion. Applicant submits that this certainly implies some human intervention. That is, without human intervention the "source" of any genetic information in a gene portion is not an issue.

Moreover, the source identification information is "for identifying" a source of the genetic information in the gene portion. Applicant again submits that this implies some human intervention. That is, the source identification information is not likely intended for identifying genetic information without at least some human intervention. Indeed, common sense again

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dictates that some human intervention is required "for identifying" the source of the genetic information.

Further, the Examiner states that Applicant's arguments regarding a nucleotide sequence "which is added" is unpersuasive because this is new matter. Although Applicant disagrees with the Examiner, Applicant notes that the claims have been amended to replace the term "added" with "embedded", which the Examiner concedes is described in the present Application.

For example, claim 5 recites "*a nucleotide sequence which is embedded in said portion including no genetic information, and comprises source identification information for identifying a source of said genetic information in said gene portion, said nucleotide sequence being embedded so as not to affect transmission of said genetic information*". Thus, claim 5 defines DNA having a nucleotide sequence which is "embedded in" a portion of the DNA. This recitation necessarily implies some human intervention.

Applicant again points out that while the claims do not recite "added by a human", common sense dictates that human intervention is required to embed the nucleotide sequence to a portion of DNA. Therefore, the claimed DNA in which a nucleotide sequence has been embedded inherently requires human intervention and is by definition not "naturally-occurring".

In short, the notion that DNA to which a nucleotide sequence (which includes information for identifying a source of genetic information) has been embedded is naturally-occurring is contrary to common sense and is obviously incorrect. Indeed, the claims are directed to DNA (or a cell including DNA) which is a "nonnaturally occurring ... composition of matter - a product of human ingenuity - having a distinctive name, character and use" as required by *Charkraabarty*, and are, therefore, directed to patentable subject matter.

In view of the foregoing, the Examiner is respectfully requested to withdraw this rejection.

### III. THE 35 USC §112, FIRST PARAGRAPH REJECTION

Claims 5, 8-12 and 15-27 stand rejected under 35 U.S.C. §112, first paragraph. Applicant respectfully submits, however, that these claims are fully enabled.

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Specifically, although Applicant disagrees with the Examiner, as noted above, the claims of the present Application have been amended to replace the term "added" with "embedded", which the Examiner concedes is described in the present Application. Further, Applicant notes that Figure 8, for example, illustrates a nucleotide sequence being "embedded" in a portion of DNA.

Further, with respect to claim 18, Applicant submits that this claim is substantially similar to original claim 10. Further, the subject matter of claims 10 and 18 is fully described in the present Application at page 23, line 2-page 25, line 20 (e.g., see Application at Figure 4). Therefore, claim 18 is fully enabled by the present Application.

Moreover, Applicant would remind the Examiner that a claim is enabled if the specification describes the subject matter sufficiently to allow one of ordinary skill in the art to make or use the invention without undue experimentation, not without any experimentation. In this case, one of ordinary skill in the art could certainly read the specification and make or use the subject matter of claim 18 without undue experimentation.

Further, with respect to claim 27, although Applicant disagrees with the Examiner allegations, Applicant notes the claim 27 has been amended to recite "wherein said nucleotide sequence is correlated with said source identification ~~corresponds to a source of said genetic~~ information" which is described in the Application, for example, at page 4, lines 11-21.

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw this rejection.

#### IV. THE 35 USC §112, SECOND PARAGRAPH REJECTION

Claims 5, 8-12 and 15-27 stand rejected under 35 U.S.C. §112, second paragraph. Applicant respectfully disagrees with the Examiner.

Specifically, with respect to claims 5, 12 and 15, the Examiner states that "[i]t is unclear how a portion of DNA can be considered not to have genetic information when it is well known in the art that DNA is made up of nucleotides which are considered to be genetic information".

Applicant would note that the Application states that "DNA consists of a gene portion

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wherein a protein code sequence and its transcription control information are stored, and a portion wherein genetic information is not included" (Application at page 13, lines 3-6). That is, a portion of DNA having "no genetic information" is a portion other than a portion which includes "a protein code sequence and its transcription control information". Applicant respectfully submits that this is universally understood by those of ordinary skill in the art and therefore, claims 5, 12 and 15 are not indefinite.

With respect to claims 5, 8, 11-12 and 15, Applicant notes that the phrase "so as not to affect transmission of said genetic information" is inherently clear to one of ordinary skill in the art. Therefore, these claims are not rendered indefinite because of this phrase.

With respect to claims 17 and 24, Applicant again respectfully submits that use of the phrase "one of x, y and z" is common and customary claim language and is perfectly acceptable U. S. practice. The Examiner states that "the two latter rejections above have various interpretations". Applicant would respectfully disagree.

In fact, Applicant's undersigned representative would point out that of the hundreds of other cases that he has prosecuted in the USPTO, he has never had any other Examiner find this language confusing and has never had any other Examiner object to this very common and clear claim language. Therefore, Applicant is extremely puzzled by this rejection and respectfully requests that the Examiner reconsider and withdraw this rejection.

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw this rejection.

## V. THE DOLLINGER REFERENCE

The Examiner alleges that Dollinger teaches the claimed invention. Applicant submits, however, that there are elements of the claimed invention which are neither taught nor suggested by Dollinger.

Dollinger discloses methods for tagging and tracing materials using nucleic acids as taggants. The process of tagging involves altering a substance in a manner that allows for the subsequent identification of the substance by detecting the alteration which involves nucleic

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acids (Dollinger at Abstract).

However, contrary to the Examiner's allegations, Dollinger does not teach or suggest *"a nucleotide sequence which is embedded in said portion including no genetic information, and comprises source identification information for identifying a source of said genetic information in said gene portion"* as recited in claims 5 and 12 and similarly recited in claims 8, 11, and 15. As noted above, conventional DNA does not include any information therein to determine the source of a value-added gene. Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of such value-added genes (Application at page 1, line 8-page 3, line 8).

The claimed invention, on the other hand, includes a nucleotide sequence which is embedded in a portion of the DNA which includes no genetic information, and which includes source identification information for identifying a source of the genetic information in the gene portion (Application at page 11, lines 1-21; page 16, line 8-page 16; page 20, line 6-page Figure 3). The added nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party (Application at page 11, lines 9-21).

Clearly, these novel features are not taught or suggested by Dollinger. Indeed, as noted above, Dollinger merely discloses a method for tagging and tracing materials using nucleic acids as taggants. That is, the Dollinger method merely allows for a material to be tagged and traced by tagging the material with a nucleic acid taggant (Dollinger at col. 1, lines 55-60). However, this is completely different from the claimed invention which includes an embedded nucleotide which includes source identification information for identifying a source of the genetic information in the gene portion (Application at page 11, lines 1-21).

Specifically, in the present invention, the source identification information may be used to identify the source of genetic information (e.g., a value-added gene) in the gene portion. Applicant respectfully points out to the Examiner that using nucleic acid to trace a material is completely different from using an embedded nucleotide sequence to does not identify **a source of genetic information**.

Therefore, Applicant submits that there are elements of the claimed invention that are not

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taught or suggest by Dollinger. Therefore, the Examiner is respectfully requested to withdraw this rejection.

#### VI. FORMAL MATTERS AND CONCLUSION

The Examiner alleges that the corrected formal drawings submitted herein on October 16, 2003 introduce new matter. Applicant respectfully disagrees but, in order to expedite prosecution, Applicant submits herewith replacement drawing sheets for Figures 8 and 9 which address the Examiner's concerns. Specifically, the nucleotides included in the sequences other than the watermark sequence and the sequence complementary to the watermark, have been deleted from the drawings.

In view of the foregoing, Applicant submits that claims 5, 8-12 and 15-27, all the claims presently pending in the application, are patentably distinct over the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

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The Commissioner is hereby authorized to charge any deficiency in fees or to credit any overpayment in fees to Assignee's Deposit Account No. 50-0510.

Respectfully Submitted,

Date: 4/13/04



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**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that the foregoing Amendment was filed by facsimile with the United States Patent and Trademark Office, Examiner Carolyn Smith, Group Art Unit # 1631 at fax number (703) 872-9306 this 13<sup>th</sup> day of April, 2004.



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